VORTRAN Medical Technology 1, Inc.

November 16, 2007

510(k) Summary

K073261

MAY 23 2008

1. Submitter Information	VORTRAN Medical Technology 1, Inc. 21 Golden Land Court, Sacramento, CA 95834	
2. Contact Information	James Lee, Senior Vice President TEL: (800) 434-4034 FAX: (916) 648-9751	
3. Trade Name	VAR with VAR-Monitor™	
4. Common Name	Ventilator, Emergency, Powered (Resuscitator)	
5. Device Class	Class II	
6. Product Code	73 BTL	
7. Product Classification	Per CFR section 868.5925	
8. Classification Panel	Anesthesiology	
9. Predicate Device	RespirTech PRO RespirTech PRO O_2C VAR-Plus Model PCM	510(k) No.: K973975 510(k) No.: K001430 510(k) No.: K041473
10. Device Description	The VAR-*Monitor* is a battery (9 VDC) operated device that is mounted onto the VAR to monitor cycling conditions during operation.	
11. Intended Use	The device is to be used by properly trained personnel to deliver emergency, short term, constant flow - pressure cycled ventilatory support.	
12. Substantial Equivalency Evaluation	The VAR with VAR-*Monitor* meets and exceeds "Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans," ASTM Designation: F 920-93 (Reapproved 1999).	
13. Operational Characteristics	VAR-*Monitor* detects a non-cycling condition of the VAR modulator indicating that no pressure changes have occurred. When the VAR-*Monitor* is powered on and ready, the device will check for the "pressure signal." If the pressure stays unchanged for more than the preset time of eight (8) seconds, both visual and audible alarms will be activated.	

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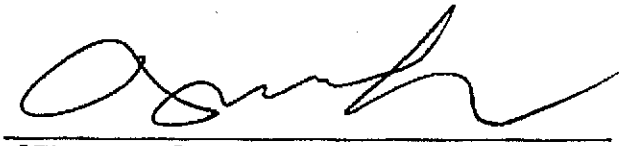
14. Clinical Application	The VAR with VAR-*Monitor* provides short term, pressure cycled, constant flow ventilatory support using either pressure control or pressure support. The device is not an ICU stand alone ventilator. Set up and use of the VAR with VAR-*Monitor* is simple. Set desired flow and adjust pressure dial to obtain desired I-time and/or tidal volume (see tidal volume chart in instructions), and adjust rate dial to obtain desired rate and I to E ratio for the VAR. Power on the VAR-*Monitor* to monitor the VAR cycling and detect any VAR non-cycling condition. This non-cycling condition will trigger the alarm (audible and visual) to notify attending personnel of an abnormal condition. Possible changing conditions could include but are not limited to: (i) increases or decreases in supply gas flow or no gas flow because tank is empty or has been turned off; (ii) patient disconnect or airway leak; or (iii) a change in patient condition. All these conditions may cause the VAR to stop cycling or stay in a spontaneous "pressure assisted" mode, waiting for the patient to trigger the next breath.
15. Clinical Tests	None
16. Adverse S & E Information	None
17. Conclusion	The VAR with VAR-*Monitor* passed all required tests and demonstrated that it meets all predetermined acceptance criteria for applicable standards. In conclusion, the modified VAR with VAR-*Monitor* is substantially equivalent (SE) to legally marketed predicate devices.



[Signature]

November 16, 2007

[Dated]

James Lee

[Typed Name]

Senior Vice President

[Title]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2008

Mr. James Lee
Senior Vice President
VORTRAN Medical Technology 1, Incorporated
21 Golden Land Court
Sacramento, California 95834

Re: K073261
Trade/Device Name: VAR with VAR-Monitor
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: II
Product Code: BTL
Dated: April 23, 2008
Received: April 28, 2008

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K073261**

Device Name: **VAR with VAR-Monitor**

Indications For Use:

The device is to be used by properly trained personnel to deliver emergency, short term, constant flow - pressure cycled ventilatory support.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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